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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

SPECTRUM PHARMACEUTICALS, INC. AND UNIVERSITY OF STRATHCLYDE,

Plaintiffs and Counterclaim Defendants,

v.

SANDOZ INC.,

Defendant and Counterclaimant.

CASE NO. 2:12-cv-00111-GMN-NJK

DEFENDANT SANDOZ INC.'S MOTION *IN LIMINE* TO EXCLUDE THE TESTIMONY OF ROLF HENEL

PUBLIC VERSION OF MOTION FILED UNDER SEAL

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INTRODUCTION

Sandoz moves *in limine* to exclude the testimony of Plaintiffs' expert Mr. Rolf Henel regarding secondary considerations of non-obviousness, including commercial success and long-felt need, on the basis that this testimony falls far short of satisfying Federal Rule of Evidence 702. To offer admissible opinion testimony on that subject, an expert must tie the alleged success to the patent-in-suit. At his deposition, Mr. Henel expressly admitted that he cannot establish this required link:

[redacted]

(Declaration of Jessica A. Roberts ("Roberts Decl.") Ex. 1 (Henel Dep.Tr. at 55:22-56:12).)

Additionally, Mr. Henel's report and deposition testimony demonstrate that he does not meet the threshold requirements for providing expert testimony, because his opinions: (1) are based on inadmissible personal beliefs; (2) lack objective data and cannot be tested; and (3) are contrary to the methodology used to determine commercial success under patent law. Because Mr. Henel cannot establish the critical nexus required for secondary considerations and his testimony fails to meet the basic requirements of Rule 702, Mr. Henel's testimony should be excluded.

LEGAL STANDARDS

The trial court's discretion to preclude inadmissible expert testimony is not subject to dispute. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). Before an expert can testify, the Court must "ensure that any and all scientific testimony or evidence admitted is not only relevant, but [also] reliable." *Id.* at 589. "This entails a preliminary assessment of whether

the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *Gen.Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

Federal Rule of Evidence 702 provides that expert testimony is admissible only if: "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. This rule incorporates the amendments made in response to *Daubert* and its progeny. *Aevoe Corp. v. Ae Tech Co., Ltd.*, No. 2:12:-cv-00053-GMN-NJK, 2014 U.S. Dist. LEXIS 117197, at *5 (D. Nev. Aug. 20, 2014).

Plaintiffs bear the burden of proving that Mr. Henel's testimony is competent, relevant, and reliable, consistent with Federal Rule of Evidence 702. *See* Advisory Committee Notes, 2000 Amendments, Fed. R. Evid. 702 ("[T]he admissibility of all expert testimony is governed by the principles of Rule 104(a). Under that Rule, the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence.") (citing *Bourjaily v. United States*, 483 U.S. 171 (1987)); *see also Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 466 (9th Cir. 2014) ("*Daubert* continues to require that the proponent of expert testimony lay a proper foundation, but now laying a proper foundation means establishing relevancy and reliability rather than mere general acceptance."), *cert. denied*, 135 S. Ct. 55 (2014).

At trial, Sandoz will present evidence regarding the obviousness of the asserted claims. It is anticipated that Plaintiffs will attempt to rebut this evidence with the testimony of Mr. Henel regarding "secondary considerations of non-obviousness." In his report and at his deposition, Mr. Henel stated that [redacted]

[redacted]

[redacted].[1] (*See, e.g.*, Roberts Decl. Ex. 2 (Henel Expert Report ¶ 19).) Under the controlling patent law, "[e]vidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006); *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) (noting that it is the patentee's burden to demonstrate the commercial success). Thus, commercial success "is relevant in the obviousness context only if there is proof that the sales [of a product] were a direct result of the unique characteristics of the claimed invention." *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996); *see also Riverwood Int'l Corp. v. Mead Corp.*, 212 F.3d 1365, 1367 (Fed. Cir. 2000) (commercial success of a product of no probative value when it is "attributable to factors outside the scope of the claims").

Importantly, when more than one patent covers a product, the commercial success of each patent must be considered individually. *See Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) (affirming finding of obviousness of one patent-at-issue where district court determined that commercial success of the product was attributable mostly to design elements disclosed in the prior art second patent-at-issue); *see also McNeil-PPC, Inc. v. Perrigo Co.*, 516 F. Supp. 2d 238, 254-55 (S.D.N.Y. 2007) (Fed. Cir. 2008) (no commercial success where it is "difficult to attribute whatever commercial success Pepcid Complete may enjoy to any one of the three patents" that cover the product) , *aff'd*, 274 F. App'x 899 (Fed. Cir. 2008); *Am. Standard, Inc. v. York Int'l Corp.*, 244 F. Supp. 2d 990, 996 (W.D. Wis. 2002) (finding no nexus between commercial success and the '190 patent when "[t]estimony given addressed the benefits of both the '560 and '190 patents, and did not show the '190 patent contributing significantly *by itself* to plaintiffs' success." (emphasis added)). Here, the Merck Eprova patents were directed at methods for producing levoleucovorin, were relevant, but unaccounted for by Mr. Henel.

Although this is a bench trial, expert testimony that is not reliable, not relevant, or a waste

[1] Notably, the patent-at-issue, U.S. Patent No. 6,500,829, did not issue until many years later, on December 31, 2002. For purposes of this motion, Sandoz will collectively refer to the pending application that was licensed by American Cyanamid and U.S. Patent No. 6,500,829 as "the '829 patent."

of judicial resources may be precluded. Indeed, in non-jury cases such as this one, "the district judge is given great latitude in the admission or exclusion of evidence." *See Ollier v. Sweetwater Union High Sch. Dist.*, 768 F.3d 843, 860 (9th. Cir. 2014) (quoting *Hollinger v. United States*, 651 F.2d 636, 640 (9th Cir. 1981) (no abuse of discretion in excluding expert testimony based on personal opinions and speculation rather than systematic assessment). Applying Federal Rule of Evidence 702, district courts have excluded an expert's opinion of commercial success where (1) an expert has failed to demonstrate a "nexus" between the evidence of success and the merits of the claimed inventions, and (2) the data upon which an expert relied was fundamentally flawed. *See Accentra, Inc. v. Staples, Inc.*, No. CV-07-5862 ABC, 2010 WL 8569058, at *5 (C.D. Cal. Nov. 1, 2010); *see also Cot'n Wash. Inc. v. Henkel Corp.*, No. 12-650 SLR, 2014 WL 4245871, at *16-17 (D. Del. Aug. 26, 2014) (excluding expert's opinions regarding secondary considerations of non-obviousness for failing to establish a nexus and relying on materials that were not submitted to the court). Because Plaintiffs cannot carry their burden to show that Mr. Henel's opinions are relevant, reliable, or based on a systematic assessment of the evidence as required under Federal Rule of Evidence 702, Plaintiffs should be precluded from offering his opinions regarding commercial success at trial.

ARGUMENT

I. MR. HENEL ADMITS HE CANNOT DEMONSTRATE THE REQUIRED NEXUS BETWEEN THE '829 PATENT AND ANY ALLEGED SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

A. Mr. Henel's Opinion Regarding Commercial Success Should Be Excluded for Failure to Establish a Nexus to the Claimed Invention

Evidence of commercial success, defined by significant sales in a relevant market, is only significant if commercial success is "due to the merits of the claimed invention beyond what was readily available in the prior art." *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2013) (quoting *J.T. Eaton & Co. v. Alt. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997)). Because Mr. Henel offers no evidence that levoleucovorin sales, in any time frame, were due to the specific characteristics of the compositions claimed in the '829 patent, his opinions should be excluded under Rule 702. In fact, Mr. Henel makes no attempt to establish the required

nexus between the claimed invention and alleged commercial success, as required by the Federal Circuit. [redacted]

While the Federal Circuit has made clear that the commercial success must be "due to the merits of the claimed invention," *Galderma*, 737 F.3d at 740, [redacted] For example, when asked whether Mr. Henel had ever done a commercial success analysis of whether sales were attributable to a claimed invention, Mr. Henel replied, [redacted] (Roberts Decl. Ex. 1 (Henel Dep. Tr. at 54:21-55:2).) Later, Mr. Henel confirmed that he did not believe a financial analysis of the performance of a drug [redacted]

[redacted]

(*Id.* at 55:22-56:12.)

It is no surprise, therefore, that Mr. Henel did not try to support his opinion of commercial success of the levoleucovorin drug with a nexus to the '829 patent. At his deposition, Mr. Henel was asked whether his opinion about commercial success referred to the '829 patent or to the product. [redacted] (*Id.* at 49:13-17.) When asked whether he had tried to assess the contribution of the '829 patent to the product's

commercial success, [redacted]:

[redacted]

(*Id.* at 52:19-24.)

The '829 patent contains only composition claims, not method claims. There are other patents that cover methods of making levoleucovorin. Mr. Henel admitted that the methods used in the '829 patent specification are [redacted] (*Id.* at 94:16-96:6.) He further admitted that a competing set of patents from Merck Eprova, which issued in the U.S. in 1991, provided [redacted] compared to the University invention. (*Id.* at 97:17-21.) But when asked whether he did [redacted] (*Id.* at 53:17-23; *see also id.* at 60:9-22.) [redacted] (*Id.* at 50:15-51:23.) In sum Mr. Henel could neither attribute all of Lederle's sales only to the composition claims of the '829 patent, nor allocate what portion of alleged commercial success should be attributed to the '829 patent.

Without evidence that the alleged commercial success is due to the claimed invention, Mr. Henel's opinion must be excluded. Evidence of commercial success alone—absent evidence of a nexus to the claimed invention—is irrelevant. *See Ormco*, 463 F.3d at 1312 (if the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant). Moreover, expert testimony does not meet the requirements of Rule 702 when such testimony fails to establish a nexus. In *Accentra*, a district court in the Ninth Circuit granted a motion similar to this one where the expert's analysis "suffer[ed] from serious flaws implicating the nexus requirement." 2010 WL 8569058, at *3. Like Mr. Henel, the witness in that case discussed the products generally "and made no effort to attribute any commercial success to any

particular patented invention." *Id.* In *Cot'n Wash*, the court also excluded testimony under Rule 702 when the witnesses failed to establish a nexus for commercial success purposes. 2014 WL 4245871, at *16-17.

B. Mr. Henel's Opinion Regarding Long-Felt But Unmet Need Should Also Be Excluded

While the nexus requirement is commonly discussed in connection with commercial success, it also applies to "other secondary considerations." *Ormco*, 463 F.3d at 1311-12. One such secondary consideration is "whether the *claimed invention* satisfied a long felt need." *Sjolund v. Musland*, 847 F.2d 1573, 1582 (Fed. Cir. 1988) (emphasis in original). In *Ormco*, the Federal Circuit noted there was no probative evidence of long-felt need when the evidence failed to link the product's success to claimed features. 463 F.3d at 1313. In his report, Mr. Henel opines that [redacted] (*See* Roberts Decl. Ex. 2 (Henel Expert Report ¶¶ 55-61).) Yet, Mr. Henel has done nothing to connect the sales to the claims of the '829 patent or to exclude patents or other factors contributing to the alleged success. (*See supra* I.A.)

II. MR. HENEL'S PROPOSED TESTIMONY SHOULD BE EXCLUDED BASED ON ADDITIONAL FLAWS UNDER RULE 702

Federal Rule of Evidence 702 "demands that expert testimony relate to scientific, technical or other specialized knowledge, which does not include unsubstantiated speculation and subjective beliefs." *Diviero v. Uniroyal Goodrich Tire Co.*, 114 F.3d 851, 853 (9th Cir. 1997) (citing *Daubert*, 509 U.S. at 590). When an expert's opinion does not satisfactorily explain the reasoning behind his opinions and fails to take into account other relevant issues, a district court may properly consider these opinions unsubstantiated, subjective, and unhelpful to the trier of fact. 114 F.3d at 853. Mr. Henel's opinions fail to meet Rule 702 for the additional reasons that they are based upon his personal beliefs, unsupported data, and an improper methodology under patent law.

A. Mr. Henel Offers Inadmissible Personal Opinions

As the Ninth Circuit recently reaffirmed, personal opinion testimony is inadmissible as a

matter of law under Rule 702. *Ollier*, 768 F.3d at 861. In *Ollier*, the Ninth Circuit affirmed the district court's decision to exclude the testimony of a retired school superintendent who would have testified about the finances of schools. The district court excluded the testimony when it could not "discern what, if any method, he employed at arriving at his opinions," because his "conclusions appear to be based on his personal opinions and speculation rather than on a systematic assessment" of the evidence. *Id.* at 860. Much like the witness in *Ollier*, Mr. Henel's testimony should be excluded because he relied on his personal opinions rather than a systematic assessment of the evidence.

As he explained at his deposition, Mr. Henel came to his conclusions regarding commercial success without reference to the evidence or the applicable patent law standards. Mr. Henel actually testified that [redacted] (Roberts Decl. Ex. 1 (Henel Dep. Tr. at 216:21-25).) Mr. Henel admitted that he is neither an economist, nor an expert in economic analysis. (*Id.* at 29:10-13.) In fact, Mr. Henel had the most minimal course work in economics—his education being limited to one sophomore-level economics course in college. (*Id.* at 29:14-30:5.) Having no economic training or qualifications, including no graduate-level education in economics, Mr. Henel relies solely on his own personal experience with a drug company that marketed a levoleucovorin product in the 1990s.

When asked how he formed his opinion regarding commercial success, Mr. Henel testified that he knew without looking at data:

[redacted]

[redacted]

(*Id.* at 113:15-114:8.)

Mr. Henel relied on his own personal recollection, because he is unqualified to perform the methodological approach required by Rule 702. For example, when asked whether he did anything in his analysis to control for an increase in promotional efforts, Mr. Henel said that he did not [redacted] (*Id.* at 131:14-23.) When pressed on the topic, Mr. Henel admitted that he did [redacted]. (*Id.* at 132:1-133:5.)

Plaintiffs' counsel tried without success to rehabilitate Mr. Henel. Plaintiffs' counsel asked when Mr. Henel first determined that the product was a commercial success, and Mr. Henel testified that he came to that conclusion within a year of the levoleucovorin product's introduction in Italy in the 1990s. (*Id.* at 204:12-205:2.) Plaintiffs' counsel also asked whether Mr. Henel took into account any "business factors" in coming to that decision, and [redacted] (*Id.* at 205:3-208:22.) When Sandoz's counsel followed up, Mr. Henel confirmed that these were all his personal opinions developed at the time. (*Id.* at 214:12-16.) Mr. Henel also confirmed that such details are lacking from his report:

[redacted]

[redacted]

(*Id.* at 218:5-24.)

Moreover, to the extent that Mr. Henel's opinion is based upon his personal role in the sales of levoleucovorin, he admitted that he did not control for bias, and [redacted] (*Id.* at 89:15-90:6.)

Any trial testimony from Mr. Henel, based on his admissions, would be his personal opinions as an unqualified and biased former employee of the company that sold levoleucovorin in the early 1990s. It is not the systematic review of objective facts under the applicable law required by Rule 702.

B. Mr. Henel's Opinions Lack Objective Data and Cannot Be Tested

Mr. Henel's opinions are also inadmissible as being conclusory, based on unverifiable sources, and without citation to objective data. Federal Rule of Evidence 702(b) requires that expert opinions must be based upon facts or data. It is proper to exclude testimony where "there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec.*, 522 U.S. at 146. Such a decision may take into account whether the evidence upon which the expert relied was sufficient, whether individually, or in combination, to support the conclusions. *Id.* at 146-47. When a witness is relying on underground knowledge that is otherwise untested and unknown, the Ninth Circuit has held that such an "opinion based on such unsubstantiated and undocumented information is the antithesis of the scientifically reliable expert opinion admissible under *Daubert* and Rule 702." *Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1423 (9th Cir. 1998).

Mr. Henel makes subjective assessments without the support of objective data throughout his report. These subjective assessments include opinions on key issues such as the relative sales of leucovorin and levoleucovorin as well as the profitability of leucovorin. [redacted] (Roberts Decl. Ex. 2 (Henel Expert Report ¶ 35.) At his deposition, Mr. Henel

admitted that this statement was based on nothing more than the recollection of another person that the [redacted] (Roberts Decl. Ex. 1 (Henel Dep. Tr. at 99:12-21) (emphasis added); *see also* Roberts Decl. Ex. 3 (Plaintiffs' Third Am. Initial Rule 26(a)(1) Disclosures (failing to list such a witness).)

Similarly, Mr. Henel's report stated without citation that [redacted] (Roberts Decl. Ex. 2 (Henel Expert Report ¶ 62).) But at his deposition, Mr. Henel explained that he made this statement based in part on [redacted] (Roberts Decl. Ex. 1 (Henel Dep. Tr. at 186:21-187:4).) Furthermore, Mr. Henel admitted that he [redacted] to do additional analysis regarding the commercial success in Japan. (*Id.* at 187:21-24.)

In addition, the Henel Report repeatedly mentions a high profit margin without citing any supporting data. (Roberts Decl. Ex. 2 (Henel Expert Report ¶¶ 35, 53).) In his report, Mr. Henel states that [redacted] (*Id.* ¶ 53.) Mr. Henel also stated that [redacted] (*Id.* ¶ 35.) At his deposition, Mr. Henel estimated that profit margin as [redacted] but again he could provide no supporting data. (Roberts Decl. Ex. 1 (Henel Dep. Tr. at 169:7-12).)

Conclusory and unsubstantiated expert testimony should be excluded. *See Diviero*, 114 F.3d at 853. In *Cot'n Wash*, the district court excluded the expert's opinion on licensing as a secondary consideration of non-obviousness where the expert failed to provide "proof that the license details were valid or provide any other license details." 2014 WL 4245871, at *16. The *Cot'n Wash* court also excluded testimony regarding copying where the expert referenced evidence, but it was not submitted to the court for review. *Id.* at *17. In this case, it is impossible

to know whether the vague, subjective [redacted] information relied upon by Mr. Henel is accurate. [redacted] (Roberts Decl. Ex. 1 (Henel Dep. Tr. at 99:12-21; 187:21-24).) Mr. Henel's testimony is similar to relying on the underground knowledge that rendered the expert's opinion inadmissible in *Cabrera*. 134 F.3d at 1423. Because Mr. Henel's opinions are not grounded in verifiable facts, they cannot be helpful to the fact finder and should be excluded.

C. Mr. Henel's Opinions Are Contrary to the Methodology Required by Patent Law

Mr. Henel's opinions contradict the methodology set out by the Federal Circuit and the U.S. Patent and Trademark Office ("PTO"). For example, Federal Circuit case law and the PTO both make clear that sales figures alone are not an indicator of commercial success. As the Federal Circuit explained in *In re Huang*, evidence of gross sales provides "no indication of whether this represents a substantial quantity in this market." 100 F.3d at 140. The PTO has also recognized that "gross sales figures do not show commercial success absent evidence as to market share." Manual of Patent Examining Procedure ("MPEP"), 716.03(b) IV at 700-300 (8th ed. Rev. 7/2110). Despite this controlling law, Mr. Henel did not make any attempt to analyze sales in the context of economic benchmarks. (Roberts Decl. Ex. 1 (Henel Dep. Tr. at 199:20-200:22).) Because Mr. Henel provides no "evidence as to market share," or evaluation of "what sales would normally be expected in the market," *In re Huang*, 100 F.3d at 140, his opinions cannot demonstrate commercial success under the required methodology and should be excluded.

The Manual of Patent Examining Procedure of the PTO directs:

> In considering evidence of commercial success, care should be taken to determine that the commercial success alleged is directly derived from the invention claimed, in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion in advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention.

MPEP 716.03(b) at 700-299. Again, Mr. Henel did nothing to control for factors impacting sales that are unrelated to the '829 patent:

Mr. Henel's failure to follow the most basic elements of the required methodology for determining commercial success mandates exclusion of his testimony. *Daubert*, 509 U.S. at 592-93.

CONCLUSION

Mr. Henel's unqualified testimony (1) contradicts the basic legal principals which control secondary consideration of nonobviousness; (2) consists of impermissible personal belief; (3) lacks objective data; and (4) is incapable of being tested.

Dated: December 12, 2014

By: /s/ Anders T. Aannestad

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